



APR - 3 2008

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

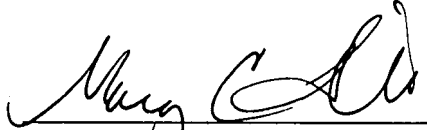
The attached application for patent term extension of U.S. Patent No. 5,317,016 was filed on December 4, 2007, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, DORIBAX™ (doripenem), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved.¹ Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

¹The filing of the application on December 4, 2007, was timely, given the NDA approval date of October 12, 2007. Applicant, however, misidentified at paragraph G on page 3 of the application the last day the application may be submitted as December 11, 2007, pursuant to 37 C.F.R. § 1.740(a)(5). Under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA approval date. The absolute deadline for filing the present PTE Application was thus December 10, 2007, or sixty days from October 12, 2007, starting the count of the sixty-day period on October 12, 2007.

Inquiries regarding this communication should be directed to Raul Tamayo at (571) 272-7728 (telephone) or (571) 273-7728 (facsimile).

A handwritten signature in dark ink, appearing to read "Mary C. Till", is written over a horizontal line.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Philip Johnson, Esq.
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